IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF OREGON

MICHAEL M. OWENS, M.D.,

Plaintiff,

v.

THE OREGON CLINIC, P.C., an Oregon professional corporation; and **PROVIDENCE HEALTH & SERVICES–OREGON**, an Oregon nonprofit corporation dba **PROVIDENCE ST. VINCENT MEDICAL CENTER**,

Defendants.

Case No. 3:22-cv-488-SI

OPINION AND ORDER

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Michael H. Simon, District Judge.

Michael M. Owens, M.D. brings this lawsuit against The Oregon Clinic, P.C. (TOC) and Providence Health & Services–Oregon, doing business as Providence St. Vincent Medical

Center (PSVMC). Dr. Owens is a gastroenterologist who previously worked for TOC and had hospital admitting privileges at PSVMC. In his Second Amended Complaint,[1] Dr. Owens alleges sixteen claims for relief, including intentional interference with economic relations, breach of contract, breach of the implied covenant of good faith and fair dealing, constructive discharge, defamation, fraudulent inducement, breach of fiduciary duty, shareholder oppression, deprivation of the common law right of fair procedure, and violations of federal antitrust law, specifically Section 1 of the Sherman Act, 15 U.S.C. § 1.

Pending before the Court is Dr. Owens's Motion for Preliminary Injunction (ECF 16), brought only against PSVMC. Dr. Owens seeks an order requiring PSVMC to withdraw a report submitted to the National Practitioner Data Bank (NPDB). The U.S. Secretary of Health and Human Services (Secretary) created the NPDB under delegations contained in the Health Care Quality Improvement Act of 1986 (HCQIA), 42 U.S.C. §§ 11101-11152. The HCQIA authorizes the Secretary to establish the NPDB "to collect and release certain information relating to the professional competence and conduct of physicians, dentists, and other health care practitioners." 45 C.F.R. § 60.1.

In its report to the NPDB, PSVMC stated that Dr. Owens surrendered his privileges with PSVMC while under investigation. Dr. Owens, however, argues that he was not under investigation when he surrendered his privileges because PSVMC had failed to take certain steps that, he contends, are required before an investigation may commence. Dr. Owens asserts that these steps are mandated by both the HCQIA and PSVMC's own Professional Staff Policies and

[1] The Second Amended Complaint (SAC) is contained within Ex. 2 of PSVMC's Notice of Removal, ECF 1-2, at 183-209.

Procedures.[2] Thus, according to Dr. Owens, PSVMC had not yet investigated Dr. Owens when PSVMC accepted his surrender of clinical privileges, making PSVMC's report to the NPDB incorrect. Solely on that basis, Dr. Owens seeks a preliminary injunction ordering PSVMC to withdraw or remedy its report.

For the reasons explained below, the Court finds that Dr. Owens has not shown a likelihood of success on the merits of his argument that PSVMC submitted an erroneous report to the NPDB that Dr. Owen's surrendered his privileges while under investigation. Because the Court finds that there is not a likelihood of success on the merits of this issue (or even serious questions going to the merits), the Court declines to consider whether Dr. Owens satisfies the other requirements needed for a preliminary injunction: irreparable injury, a favorable balance of the equities, and the public interest. Accordingly, the Court denies Dr. Owens's motion for preliminary injunction.

STANDARDS

A preliminary injunction is an "extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008). A plaintiff seeking a preliminary injunction generally must show that: (1) the plaintiff is likely to succeed on the merits; (2) the plaintiff is likely to suffer irreparable harm without preliminary relief; (3) the balance of equities supports the plaintiff; and (4) that an injunction is in the public interest. *Id.* at 20 (rejecting the Ninth Circuit's earlier rule that the

[2] Dr. Owens mistakenly refers to PSVMC's Professional Staff Policies and Procedures as "Bylaws." *See, e.g.*, Plaintiff's Motion (ECF 16) at 6 ("The terms and conditions of PSVMC's 'professional review actions' under HCQIA regarding professional conduct concerns are contained in Article VII of its Bylaws."). PSVMC's Bylaws, which are not relevant to the pending motion, are found at ECF 36 at 3-31. PSVMC's Professional Staff Policies and Procedures, which are relied on by Dr. Owens, are found at ECF 38-2.

mere "possibility" of irreparable harm was sometimes enough to support a preliminary injunction).

The Supreme Court's decision in *Winter*, however, did not disturb the Ninth Circuit's alternative "serious questions" test. *See All. for the Wild Rockies v. Cottrell*, 632 F.3d 1127, 1131-32 (9th Cir. 2011). Under this test, "'serious questions going to the merits' and a hardship balance that tips sharply toward the plaintiff can support issuance of an injunction, assuming the other two elements of the *Winter* test are also met." *Id.* at 1132. Thus, a preliminary injunction may be granted "if there is a likelihood of irreparable injury to plaintiff; there are serious questions going to the merits; the balance of hardships tips sharply in favor of the plaintiff; and the injunction is in the public interest." *M.R. v. Dreyfus*, 697 F.3d 706, 725 (9th Cir. 2012).

The already high standard for granting a preliminary injunction is further heightened when the type of injunction sought is a "mandatory injunction," which requires a defendant to perform some action, as opposed merely to refrain from doing something. *Garcia v. Google, Inc.*, 786 F.3d 733, 740 (9th Cir. 2015) (noting that the burden is "doubly demanding" for a mandatory injunction). To obtain a mandatory injunction, a plaintiff must "establish that the law and facts *clearly favor* her position, not simply that she is likely to succeed." *Id.* (emphasis in original). As explained by the Ninth Circuit:

> A preliminary injunction can take two forms. A prohibitory injunction prohibits a party from taking action and "preserve[s] the status quo pending a determination of the action on the merits." *Chalk v. U.S. Dist. Court*, 840 F.2d 701, 704 (9th Cir. 1988); *see also Heckler v. Lopez*, 463 U.S. 1328, 1333 (1983) (a prohibitory injunction "freezes the positions of the parties until the court can hear the case on the merits"). A mandatory injunction orders a responsible party to take action. A mandatory injunction goes well beyond simply maintaining the status quo [p]endente lite [and] is particularly disfavored. In general, mandatory injunctions are not granted unless extreme or very serious damage will result and are

> not issued in doubtful cases or where the injury complained of is capable of compensation in damages.

Marlyn Nutraceuticals, Inc. v. Mucos Pharma GmbH & Co., 571 F.3d 873, 878-79 (9th Cir. 2009) (cleaned up).

Finally, "[d]ue to the urgency of obtaining a preliminary injunction at a point when there has been limited factual development, the rules of evidence do not apply strictly to preliminary injunction proceedings." *Herb Reed Enters., LLC v. Florida Entmt. Mgmt., Inc*., 736 F.3d 1239, 1250 n.5 (9th Cir. 2013); *see also Johnson v. Couturier*, 572 F.3d 1067, 1083 (9th Cir. 2009).

BACKGROUND[3]

Dr. Owens is a gastroenterologist licensed to practice medicine in Oregon and Washington. SAC (ECF 1-2) at 183-84. When the present conflict began, Dr. Owens was employed by TOC and had admitting privileges at PSVMC. He also was a shareholder of TOC since 2008. *Id.* at 183.

In January 2021, Dr. Owens was working at PSVMC's Consulting Gastroenterology Service. *Id.* at 185. According to Dr. Owens, he used this opportunity to try a "new method" of inputting chart notes that he hoped would avoid potential violations of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104-191. *Id*. Under his new method, Dr. Owens would "pre-chart" certain notes about patients *before* he provided the described services to those patients. *Id.* Dr. Owens asserts that he intended to send these "pre-recorded" notes into a "pending" folder so he could return to them later in the day *after* seeing the patients and providing the services. *Id.* Instead, Dr. Owens explains, he clicked the "sign-off" button by mistake for two patients, which moved his notes for those patients into

[3] For purposes of the pending motion, the Court finds these facts by a preponderance of the evidence.

"completed work" folders. *Id*. Dr. Owens never treated, or even saw, either patient for whom he had "pre-recorded" notes. Thus, although no services had been performed, Dr. Owens prompted an automated process through which two patients would be billed as if the services had been provided to them. TOC's billing processes caught this mistake, so no patient was improperly billed for services not provided. The parties dispute the significance of Dr. Owens's actions. Dr. Owens contends that the error was one of "no harm, no foul," because neither patient was billed. PSVMC, however, considered the matter to be more serious.

On February 3, 2021, two health care providers from TOC reported these incidents to Datix, an internal PSVMC system used to report quality and other concerns about physicians. Declaration of Leanne Park (ECF 27) ¶ 2 (Park Decl.). One report was filed by Amy Caine, P.A., a health care provider with TOC and a member of PSVMC's Professional Staff. *Id.* ¶ 3. In her report, Ms. Caine stated that Dr. Owens failed to visit one of his two "pre-reported" patients despite being reminded several times throughout the day to do so. *Id.* ¶ 3, Ex. 101, at 2. The other report was filed by Brent Lee, M.D., also a health care provider with TOC and a member of the PSVMC's Professional Staff. *Id.* ¶ 4.

In his report, Dr. Lee stated that he had seen a patient on January 15, 2021, who was scheduled to have a colonoscopy with a possible capsule endoscopy. *Id.* ¶ 4, Ex. 102, at 2. Although the patient's chart showed that Dr. Owens had spoken with the patient about the upcoming exam, Dr. Lee learned that the patient had not, in fact, been seen by or consulted Dr. Owens about the upcoming procedure. *Id.* Ex. 102, at 2. In addition, as described in both written reports, Dr. Owens had "pre-recorded" that he had completed a Physical Activity Readiness Questionnaire (PARQ) with these two patients. *Id.* Ex. 101, at 2, Ex. 102, at 2. A completed PARQ is a part of the process in which a medical provider explains to a patient the

medical procedure, alternatives, and risks; answers any questions the patient may have; and documents receiving the patient's "informed consent," all before performing the described procedure. Oregon law requires these steps, including having a properly completed PARQ, for documenting informed consent. Or. Rev. Stat. § 677.097.

On February 12, 2021, David Corman, M.D., Emery Douville, M.D., and Ms. Leanne Park met to discuss the two reports about Dr. Owens. Park Decl., ¶ 5. At the time, Dr. Corman was the Chief of Medicine and Dr. Douville was the Chief of Surgery at PSVMC. *Id.* These two doctors also were members of PSVMC's Professional Staff Quality Review Committee (PQRC) as well as members of PSVMC's Medical Executive Committee (MEC), and neither worked directly with Dr. Owens. *Id.* Park was the Director of Quality Management & Medical Staff Services for Clinical Peer Review at PSVMC. *Id.* ¶ 1.

After discussing the two Datix reports about Dr. Owens, Dr. Corman, Dr. Douville, and Ms. Park agreed that the reports raised concerns of possible improper professional conduct and perhaps also concerns about clinical incompetence, at least as it related to documentation in the electronic health records. *Id.* ¶ 5. They also agreed that the reports needed to be promptly investigated and commenced an investigation under Section 3 of Article VII of PSVMC's Professional Staff Policies and Procedures. *Id.*[4] These three professionals believed that

[4] Article VII, Section 3, which is titled "Focused Review or Investigation," provides in relevant part:

> If it is determined there are significant clinical or professional conduct concerns, a focused review or investigation may be initiated. Written notice will be provided to the Member regarding the scope of evaluation when a focused review is initiated. The Member will receive feedback of the focused review findings. A summary of the events, findings and conclusions will be placed in the Member's Quality file. The conclusion may be a

Dr. Owens's misrepresentations in the medical records of these two patients could risk patient safety because other physicians might rely on the false information. *Id.* ¶ 5. Of particular concern was Dr. Owens's false statements that he had administered the required PARQ informed consent process without, in fact, having done so. *Id.* Dr. Corman, Dr. Douville, and Ms. Park also agreed that Dr. Corman, as PSVMC's Chief of Medicine, would lead this investigation, rather than the then-current chair of PSVMC's gastroenterology department, to avoid potential bias based on an earlier conflict between Dr. Owens and the department chair. *Id.* ¶ 6.

As part of the investigation of Dr. Owens, Dr. Corman and Dr. Douville agreed to interview both Ms. Caine and Dr. Lee about their Datix reports and then meet with Dr. Owens to discuss their concerns. *Id.* ¶ 7. In preparation for the interviews with Ms. Caine and Dr. Lee, Ms. Park prepared a written summary that detailed the two Datix reports, the calls between TOC and PSVMC about these concerns, and other relevant background. *Id.* Ms. Park also prepared a list of proposed interview questions. *Id.*

On February 26, 2021, Dr. Corman and Dr. Douville interviewed Ms. Caine. Declaration of David Corman (ECF 28) ¶ 4 (Corman Decl.); *see also* Declaration of Emery C. Douville (ECF 29) ¶ 4 (Douville Decl.). Ms. Caine confirmed the facts presented in her Datix report, and she also described a similar instance of concern from two years before. Corman Decl. ¶ 4. Also on February 26, Dr. Corman sent an email to Dr. Owens. *Id.* ¶ 5. In that email, Dr. Corman told Dr. Owens that Dr. Corman was sending the email in his role as Division Chief and that

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> recommendation for: a) No further action; or b) Referral with recommendation to the MEC for review and possible action.

ECF 38-2, at 30.

Dr. Owens should watch for an email from Ms. Abbie Goldberg, Medical Staff Coordinator, about setting up a meeting to discuss "some recent concerns." *Id*.

On March 1, 2021, Ms. Goldberg sent an email to Dr. Owens, asking to schedule a time when Dr. Owens could meet with Dr. Corman and Dr. Douville. Declaration of Michael Owens (ECF 18) ¶ 10 (Owens Decl.). Dr. Owens replied later that day, stating that his schedule was full but that he would soon send dates and times for when he might be available to meet. *Id.* Ex. 2, at 1. On March 5, 2021, Dr. Corman and Dr. Douville interviewed Dr. Lee, who confirmed what he had said in his Datix report. Corman Decl. ¶ 6; Douville Decl. ¶ 5.

Because Dr. Owens did not send the promised follow-up email, on March 10, 2021, Dr. Corman sent another email to Dr. Owens, emphasizing the need to meet soon and asking Dr. Owens to reach out to Ms. Goldberg to schedule that meeting. Corman Decl. ¶ 7; Corman Decl., Ex. 201, at 1. Dr. Owens replied that he would be unavailable to meet until March 30, 2021. *Id.* Also on March 10, 2021, the PSVMC PQRC recommended referring the matter involving Dr. Owens to the MEC because of the severity of the reported issues and because the scope of these issues exceeded the authority of the PQRC. Park Decl. ¶ 10.

On March 12, 2021, Dr. Owens and TOC signed a Separation Agreement. Owens Decl. ¶ 11. One of the terms of the Separation Agreement stated that Dr. Owens would not "provide services at [PSVMC] for a period of two years." Owens Decl. Ex. 3, at 2. On March 18, 2021, PSVMC learned from TOC about Dr. Owens's separation from TOC. Park Decl. ¶ 11. This information shifted the focus of PSVMC's investigation of Dr. Owens's conduct. *Id.* Because Dr. Owens was no longer employed by TOC with an active medical practice, Dr. Owens no longer satisfied several of the criteria that PSVMC requires for physicians to maintain hospital

privileges, including having an office in which to see patients and having active medical malpractice coverage. *Id.*

Because he was no longer employed with TOC, Dr. Owens had only two options: he could take "inactive" status with PSVMC, which would essentially pause his hospital privileges there until he reestablished compliance with PSVMC's requirements, or he could surrender his privileges with PSVMC. *Id.* ¶ 12. If Dr. Owens chose to take inactive status, PSVMC's investigation based on the Datix reports would continue, but Dr. Owens would still need to meet with Dr. Corman and Dr. Douville as part of that investigation. *Id.* If, however, Dr. Owens chose to surrender his privileges, PSVMC would close the investigation but would then need to report to the NPDB that Dr. Owens had surrendered his privileges while under investigation. *Id.*

On March 18, 2021, Ms. Goldberg left a voicemail message for Dr. Owens, alerting him to the fact that if he could not provide PSVMC with proof that he continued to meet PSVMC's required criteria, his status would be converted to "inactive." *Id.* ¶ 13. Dr. Owens did not immediately respond. Until this point, both Ms. Goldberg and Dr. Corman had been attempting to schedule a meeting with Dr. Owens. Although Section 2 of Article VII of PSVMC's Professional Staff Policies and Procedures contains a mechanism to require physicians to meet with PSVMC leadership, PSVMC generally first tries to allow physicians to schedule mutually convenient dates and times for meetings to avoid conflicts that may harm patient care. *Id.* ¶ 8.

On March 26, 2021, at 1:30 p.m., Dr. Owens sent an email to Ms. Goldberg, stating that it would be "fine for now" to be switched to inactive status. Park Decl. ¶ 14; Owens Decl., Ex. 4, at 2. One hour later, Ms. Goldberg replied by email, explaining to Dr. Owens the consequences of being on inactive status and noting that Dr. Owens would still have to meet with physician leadership. Park Decl. ¶ 14; Owens Decl., Ex. 4, at 1-2. Within 21 minutes, Dr. Owens

responded by email: "No need for meeting. I resign my membership." Park Decl. ¶ 14; Owens Decl., Ex. 4, at 1.

On March 31, 2021, PSVMC "emailed and overnighted" a letter to Dr. Owens explaining the consequences of his request to resign his privileges. Park Decl. ¶ 15. Among other things, PSVMC's letter told Dr. Owens that he was under investigation by PSVMC and that if he resigned, PSVMC would have to submit a report to the NPDB stating that Dr. Owens had surrendered his hospital privileges while under investigation. *Id.*; Owens Decl., Ex. 5, at 3. In that letter, PSVMC also told Dr. Owens that he would have five days, until April 5, 2021, to decide whether he still wanted to request resignation or, if he chose not to resign and instead go inactive, he would have to cooperate with the ongoing investigation. Owens Decl., Ex. 5, at 3.

The MEC met on April 1, 2021, to discuss Dr. Owens's situation, among other things. Park Decl. ¶ 16. Dr. Corman described for the MEC the "recent allegations of potential billing fraud that led to investigation" and explained the most recent developments, including Dr. Owens's pending resignation. Park Decl., Ex. 105, at 4-5. The MEC noted that an investigation of Dr. Owens was already underway, and the MEC formally appointed Dr. Corman and Dr. Douville as the MEC's investigative committee. Park Decl. ¶ 16.

On April 4, 2021, Dr. Owens sent an email to Ms. Goldberg, stating that he was *not* under investigation, and thus it was "inappropriate to say there was an investigation" in progress when he resigned. Owens Decl., Ex. 5, at 1. Dr. Owens did not ask to be placed on inactive status. *Id.* On April 5, 2021, PSVMC accepted the surrender of Dr. Owens's hospital privileges. Park Decl. ¶ 17. Shortly thereafter, PSVMC submitted its report to the NPDB, which stated that Dr. Owens had surrendered his hospital privileges on March 26, 2021, while under investigation relating to possible incompetence or improper professional conduct. Park Decl. ¶ 19; Park Decl., Ex. 106.

DISCUSSION

According to Dr. Owens, the fact that PSVMC reported to the NPDB that Dr. Owens had surrendered his privileges with PSVMC while under investigation has made it difficult for him to obtain clinical privileges at another hospital. Indeed, Dr. Owens asserts that for more than a year he has been unable to work in his chosen profession because PSVMC filed its report with the NPDB "alleging that Dr. Owens had resigned his hospital admitting privileges while under a purported 'investigation' for billing fraud." ECF 16 at 2. Dr. Owens contends that he "resigned his privileges to satisfy a non-compete clause in his separation agreement with TOC" and that he "had no knowledge of any purported 'investigation' at the time of his resignation." *Id*.

In support of his motion for preliminary injunction, Dr. Owens argues:

> [PSVMC] failed to provide Dr. Owens with the requisite notice of, an opportunity to be heard on, or even the subject matter of its alleged "investigation." This constituted a breach of its own Medical Staff Bylaws (Bylaws) and the Health Care Quality Improvement Act, 42 U.S.C. §10001, *et. seq*. (HCQIA). Given these deficiencies under the Bylaws and HCQIA, there could not have been any investigation as [PSVMC] purported. Indeed, [PSVMC's] allegations were so utterly lacking in merit, that in April 2022, the Oregon Medical Board (OMB) closed its own investigation of [PSVMC's] report with no further action being recommended. Yet, despite these facts, [PSVMC] still refuses to withdraw its false NPDB report.

Id. at 2-3.[5] In his motion, Dr. Owens seeks a mandatory injunction, requiring PSVMC "to withdraw any reports it has filed with" the NPDB. *Id*. at 2.

As discussed below, if Dr. Owens surrendered his clinical privileges with PSVMC while under investigation, federal law *requires* PSVMC to report that fact to the NPDB. Dr. Owens contends that because PSVMC had not yet informed Dr. Owens that he was under investigation

[5] As previously noted, when Dr. Owens refers to PSVMC's "Bylaws," he means PSVMC's Professional Staff Policies and Procedures. *See* n.2, supra.

and had not yet provided him with a hearing or other "due process" when he sent his email on March 26, 2021, surrendering his hospital privileges, he could not have been under investigation when he surrendered his privileges. Thus, according to Dr. Owens, PSVMC "falsely" informed the NPDB that Dr. Owens had surrendered his privileges while under investigation and the Court should order PSVMC to retract that allegedly false statement.

A. Statutory and Regulatory Framework

The HCQIA authorizes the Secretary to establish the NPDB to collect and release certain information relating to the professional competence and conduct of physicians and other health care practitioners. 45 C.F.R. § 60.1. As the Eleventh Circuit explained:

> The Data Bank prevents a physician who applies to become a member of a hospital's medical staff or for clinical privileges from being able to hide disciplinary actions that have been taken against him. . . . Information in the Data Bank is intended "only to alert . . . health care entities that there may be a problem with a particular practitioner's professional competence or conduct" because the practitioner has been the subject of a disciplinary action. . . . The Data Bank contains not only the hospital's side of the story but also the physician's response. What the requesting hospital does with the information it obtains from the Data Bank is entirely up to that hospital. It could completely discount the information, or it could back off from any professional relationship with the physician, or it could make further inquiries to determine what had actually happened.

Leal v. Sec'y, U.S. Dep't of Health & Hum. Servs., 620 F.3d 1280, 1283-84 (11th Cir. 2010).

Under the applicable regulations, health care entities must report to the NPDB certain information about health care practitioners. *Id*., § 60.2. A hospital is a "health care entity." *Id*., § 60.3. Each health care entity must report to the NPDB these actions:

> (i) Any professional review action that adversely affects the clinical privileges of a physician or dentist for a period longer than 30 days, [or]
>
> (ii) *Acceptance of the surrender of clinical privileges or any restriction of such privileges by a physician or dentist*:

> (A) *While the physician or dentist is under investigation by the health care entity relating to possible incompetence or improper professional conduct*, or
>
> (B) In return for not conducting such an investigation or proceeding, or

45 C.F.R. § 60.12(a)(1) (emphasis added).[6]

The Secretary's implementing regulations define "professional review action" as an action or recommendation of a health care entity

> taken in the course of professional review activity based on the professional competence or professional conduct of an individual health care practitioner which affects or could affect adversely the health or welfare of a patient or patients and which adversely affects or may adversely affect the clinical privileges or membership in a professional society of the health care practitioner.

Id., § 60.3 (cleaned up). The regulations define "professional review activity" as

> an activity of a health care entity with respect to an individual health care practitioner: (1) To determine whether the health care practitioner may have clinical privileges with respect to, or membership in, the entity; (2) To determine the scope or conditions of such privileges or membership; or (3) To change or modify such privileges or membership.

Id. The regulations do not define "investigation," as that term used in § 60.12(a)(1).

[6] These regulations are based on statutory provisions in the HCQIA. Information required to be reported under 42 U.S.C. § 11133 must be reported as the Secretary prescribes. *Id.* § 11134. Similarly, whenever a hospital "takes a professional review action that adversely affects the clinical privileges of a physician for a period longer than 30 days" *or* "accepts the surrender of clinical privileges of a physician—(i) while the physician is under an investigation by the entity relating to possible incompetence or improper professional conduct, or (ii) in return for not conducting such an investigation or proceeding," the hospital must report the name of the physician involved, a description of the acts or omissions or other reasons for the action or, if known, for the surrender, and such other information respecting the circumstances of the action or surrender as the Secretary deems appropriate. *Id.* § 11133. Although the HCQIA defines "professional review action," it does not define "investigation." *Id.* § 11151.

The Secretary, however, has published a Guidebook (Guidebook) to serve as a "policy manual" for the NPDB and "to inform the U.S. health care community and others about the [NPDB] and the requirements established by the laws governing the NPDB," including the HCQIA. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, HEALTH RESOURCES AND SERVICES ADMINISTRATION. NPDB GUIDEBOOK. ROCKVILLE, MARYLAND: U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, at A-1 (2018).[7] The Guidebook states: "The creation of the NPDB represented an important step by the U.S. government to enhance professional review efforts by making available to eligible entities and individuals certain information concerning medical malpractice payments and adverse actions." *Id*. at A-2.

Chapter E of the Guidebook is titled "Reports" and contains a subchapter titled "Reporting Adverse Clinical Privileges Actions." In that subchapter, the Guidebook explains:

> Hospitals and other health care entities must report adverse clinical privileges actions to the NPDB that meet NPDB reporting criteria – that is, any professional review action that adversely affects the clinical privileges of a physician or dentist for a period of more than 30 days *or the acceptance of the surrender of clinical privileges*, or any restriction of such privileges by a physician or dentist, (1) *while the physician or dentist is under investigation by a health care entity relating to possible incompetence or improper professional conduct*, or (2) in return for not conducting such an investigation or proceeding. Clinical privileges include privileges, medical staff membership, and other circumstances (e.g., network participation and panel membership) in which a physician, dentist, or other health care practitioner is permitted to furnish medical care by a health care entity.

Id. at E-31 (emphasis added). The Guidebook repeats that "[h]ospitals and other eligible health care entities must report . . . [a]cceptance of a physician's or dentist's surrender or restriction of

[7] Dr. Owens refers to the Guidebook as the "NPDB Handbook." *See* Decl. of H. Laforest (ECF 17) ¶ 4. They are the same thing.

clinical privileges while under investigation for possible professional incompetence or improper professional conduct[.]" *Id*. at E-32.

This subchapter also contains a section titled "Investigations." That section states, in relevant part:

> Investigations should not be reported to the NPDB. *However, a surrender of clinical privileges or failure to renew clinical privileges while under investigation or to avoid investigation must be reported.*
>
> *NPDB interprets the word "investigation" expansively*. It may look at a health care entity's bylaws and other documents for assistance in determining whether an investigation has started or is ongoing, but it retains the ultimate authority to determine whether an investigation exists. *The NPDB considers an investigation to run from the start of an inquiry until a final decision on a clinical privileges action is reached. In other words, an investigation is not limited to a health care entity's gathering of facts or limited to the manner in which the term "investigation" is defined in a hospital's bylaws. An investigation begins as soon as the health care entity begins an inquiry* and does not end until the health care entity's decision-making authority takes a final action or makes a decision to not further pursue the matter.
>
> A routine, formal peer review process under which a health care entity evaluates, against clearly defined measures, the privilege-specific competence of all practitioners is not considered an investigation for the purposes of reporting to the NPDB. *However, if a formal, targeted process is used when issues related to a specific practitioner's professional competence or conduct are identified, this is considered an investigation for the purposes of reporting to the NPDB.*
>
> A health care entity that submits a clinical privileges action based on surrender, restriction of, or failure to renew a physician's or dentist's privileges while under investigation should have evidence of an ongoing investigation at the time of surrender, or evidence of a plea bargain. The reporting entity should be able to produce evidence that an investigation was initiated prior to the surrender of clinical privileges by a practitioner. Examples of acceptable evidence may include minutes or excerpts from committee meetings, orders from hospital officials directing an investigation, or notices to practitioners of an investigation (*although there is no*

> *requirement that the health care practitioner be notified or be aware of the investigation*).

Id. at E-36 through E-37 (emphasis added). *See also* E-37 ("For NPDB reporting purposes, the term 'investigation' is *not* controlled by how that term may be defined in a health care entity's bylaws or policies and procedures." (emphasis added)).[8]

Because neither the HCQIA nor the implementing regulations define "investigation," it is also appropriate to look to the ordinary meaning of that word. *See Animal Legal Def. Fund v. U.S. Dep't. of Agric.*, 988 F.3d 1131, 1134 (9th Cir. 2019) ("When a statute does not define a term, we typically give the phrase its ordinary meaning." (quoting *FCC v. AT&T*, 562 U.S. 397, 403 (2011))). In *Doe v. Rogers*, the court defined "investigation" in this context to mean a "systemic examination." 139 F. Supp. 3d at 137 (citing Merriam-Webster Dictionary, *available at* https://www.merriam-webster.com/dictionary/investigation). Further, to "examine" is to "inquire into carefully." Merriam-Webster Dictionary, *available at* https://www.merriam-webster.com/dictionary/examine. Thus, an "investigation" is a careful and systemic inquiry.

Legislative history also helps clarify the problem that Congress was attempting to address when it required disclosure by a hospital of the acceptance of the surrender of clinical privileges of a physician while the physician is under an "investigation" by the hospital relating to possible incompetence or improper professional conduct. Congress included the "surrender while under investigation" provision to fill a loophole where physicians under investigation and health care entities "resort to 'plea bargains' in which a physician agrees to such a surrender in return for the health care entity's promise not to inform other health care entities about the circumstances of

[8] Several cases also have looked to the Guidebook for guidance on interpreting the term "investigations" in this context. *See Doe v. Leavitt*, 552 F.3d 75, 79-80 (1st Cir. 2009); *Doe v. Rogers*, 139 F. Supp. 3d 120, 133-37 (D.D.C. 2015); *Simpkins v. Shalala*, 999 F. Supp. 106, 112-15 (D.D.C. 1998).

the physician's surrender of privileges." H.R. Rep No. 99-903, pt. 1, at 15. At the time of the law's passage, a major problem facing the health care industry was that "corrupt and incompetent health care providers could avoid disciplining" by accepting these "plea bargains" while their misconduct was still under investigation. *Health Care Quality Improvement Act of 1986: Hearing on H.R. 5540 Before the Subcomm. on Civ. and Const. Rights of the H. Comm. on the Judiciary*, 99th Cong. 34 (1986) (statement of Richard P. Kusserow, Inspector General, Dep't of Health and Human Services). Because the investigation would close before it was fully resolved, no record of the physician's incompetence would exist, or would exist only at the state level. Incompetent physicians could then move from state to state, continually gaining privileges at health care entities where their incompetence could harm an ever-increasing number of patients at unwitting hospitals. Hospitals often signed such "plea bargains" to avoid the expenditure of time and resources on an investigation and to avoid potential lawsuits that could arise out of disciplining physicians. Thus, the HCQIA requires a report to the NPBD whenever a sufficiently adverse disciplinary action (e.g., a professional review action) is taken against a physician or when a physician resigns clinical privileges while under investigation, among other circumstances, even before any disciplinary action has occurred. 42 U.S.C. § 11133(a).

B. Application

Dr. Owens makes two independent arguments in support of his assertion that he was not, in fact, under investigation by PSVMC when he surrendered his hospital privileges. First, Dr. Owens contends that the HCQIA requires "adequate notice and hearing procedures" before an investigation may be commenced, but none were provided. Second, he states that PSVMC's Professional Staff Policies and Procedures similarly require notice and appropriate procedures before an investigation may be commenced but none were given. Both arguments lack merit.

1. The HCQIA and Its Implementing Regulations

The HCQIA provides health care entities with *immunity* from damages resulting from their professional review actions, provided those actions meet certain specified standards. 42 U.S.C. § 11111(a). To receive immunity from damages under § 11111(a), a professional review action must be taken:

> (1) in the reasonable belief that the action was in the furtherance of quality health care,
>
> (2) after a reasonable effort to obtain the facts of the matter,
>
> (3) *after adequate notice and hearing procedures are afforded to the physician involved or after such other procedures as are fair to the physician under the circumstances*, and
>
> (4) in the reasonable belief that the action was warranted by the facts known after such reasonable effort to obtain facts and after meeting the requirement of paragraph (3).

Id. § 11112(a) (emphasis added). Thus, if "adequate notice and hearing procedures" (or other fair procedures) were not given, then a health care entity would not receive the benefit of immunity from damages for an adverse professional action that § 11111 provides. Further, § 11112 expressly states that nothing in that section may be construed as requiring the notice and hearing procedures referred to in subsection (a)(3) "where there is no adverse professional review action taken." *Id.* § 11112(c)(1)(A). Thus, under subsection (c)(1)(A), notice and hearing procedures are not required if no "adverse professional review action" is taken.

Dr. Owens conflates "professional review action" with "investigation," contending that they mean the same thing. They do not. As noted, the regulations define "professional review action" as an action or recommendation of a health care entity taken during professional review activity based on the professional competence or professional conduct of an individual health care practitioner which adversely affects (or could adversely affect) the health or welfare of a

patient or patients and which adversely affects (or could adversely affect) the clinical privileges or membership in a professional society of the health care practitioner. 45 C.F.R. § 60.3. As also noted, the regulations define "professional review activity" as an activity of a health care entity with respect to an individual health care practitioner (1) to determine whether the health care practitioner may have clinical privileges with respect to, or membership in, the entity, (2) to determine the scope or conditions of such privileges or membership; or (3) to change or modify such privileges or membership. *Id*.

An investigation may very well be a professional review activity that could lead to a professional review action, but the investigation itself is not a professional review action. Thus, the notice and hearing procedures required for a professional review action to receive the benefits of immunity from damages are not required "where there is no adverse professional review action taken," which is the situation when an investigation does not result in a professional review action. 42 U.S.C. § 11112(c)(1)(A).

In addition, 42 U.S.C. § 11133(a)(1) (as well as 45 C.F.R. § 60.12(a)(1)) distinguishes a "professional review action" from acceptance of surrender of privileges while a physician is under "investigation." This distinction implies and reinforces the conclusion that an "investigation," by itself, is not a professional review action. Thus, there is no requirement of either notice or adequate hearing procedures before an "investigation" can be commenced—or even while it is proceeding. Finally, this conclusion that an investigation is distinct from a professional review action is confirmed by the legislative history of the HCQIA.

The House Committee Report's comment on section 11112(c) clarifies: "Under this provision, there is no requirement that due process meet a test of 'adequacy' where no adverse professional review action is taken (e.g. *an investigation* resulting in a decision not to take a

professional review action) . . . ." H.R. Rep No. 99-903, pt. 1, at 11 (emphasis added). *See also Mathews v. Lancaster Gen. Hosp.*, 883 F. Supp. 1016, 1027-28 (E.D. Pa. 1995), *aff'd*, 87 F.3d 624 (3d Cir. 1996) ("Reading all of these statutory provisions together, we must agree with defendants that, as applied in the context of a privileges restriction, the term 'professional review activity' refers to preliminary investigative measures taken in 'a reasonable effort to obtain the facts' relevant to a possible change in a physician's privileges, while the term 'professional review action' refers to the decision that results from a review of the facts obtained.").

2. PSVMC's Professional Staff Policies and Procedures

As an independent argument purporting to show that he was not under investigation when he surrendered his hospital privileges at PSVMC, Dr. Owens relies on several provisions in PSVMC's Professional Staff Policies and Procedures. Dr. Owens cites Article VII, Section 3 of PSVMC's Professional Staff Policies and Procedures, titled "Focused Review or Investigation." Section 3 provides:

> If it is determined there are significant clinical or professional conduct concerns, *a focused review or investigation may be initiated. Written notice will be provided to the Member regarding the scope of evaluation when a focused review is initiated*. The Member will receive feedback of the focused review findings. A summary of the events, findings and conclusions will be placed in the Member's Quality file. The conclusion may be a recommendation for: a) No further action; or b) Referral with recommendation to the MEC for review and possible action.

ECF 38-2, at 30 (emphasis added).

Dr. Owens argues that a "focused review" is the same thing as an "investigation" and that this section requires written notice be provided to a Member "regarding the scope of evaluation when a focused review is initiated." This section, however, does not state that a focused review is the same thing as an investigation. Further, the section expressly states that written notice

describing the scope of evaluation is required when a "focused review" is initiated. Section 3 does not impose a similar requirement when an "investigation" is initiated.

Dr. Owens also cites Article VII, Section 2 the PSVMC's Professional Staff Policies and Procedures. That section is titled "Interview/Special Appearance." It provides:

> *The Member may be required to meet and confer with the President, Department Chair or committee appointed to investigate the clinical or professional conduct concerns.* The Member will be given written notice at least seven days in advance of the meeting. The notice will include the date, time and place of the meeting, a statement of the issue, that the Member's appearance is mandatory and failure to appear will result in automatic suspension. At this meeting, the Member will be invited to discuss the concern. This meeting is not a procedural right of the Member and need not be conducted according to the procedural rules provided in the Fair Hearing Plan. A written report is maintained in the Member's Quality file summarizing the events, findings and conclusions, with copies to the President, Department Chair, and MEC. The conclusion may be a recommendation for: a) No further action; b) A focused review or investigation with documented findings (defined in Section 3); or c) Referral with recommendation to the MEC for review and possible action and to the HCC for information.

ECF 38-2, at 29 (emphasis added).

Dr. Owens argues that under Section 2, seven days' written notice describing the "statement of the issue" must be provided to a physician if the physician is compelled to attend a meeting with PSVMC's leadership. PSVMC, however, had not yet "compelled" Dr. Owens's attendance at a meeting. Thus, any obligation by PSVMC to provide Dr. Owens with "a statement of the issue" had not yet become ripe. Further, the text of Section 2 implies that a committee may be appointed to investigate a Member and indeed begin an investigation without any notice needing to be provided to that Member so long as the Member is not compelled to attend a meeting without adequate notice.

Dr. Owens cites to other provisions in PSVMC's documents as well, and the Court is not persuaded by those provisions either. But even if, for the sake of argument, a PSVMC document were clearly to require that before an investigation commences, PSVMC must give a doctor notice, that would not affect PSVMC's obligation to provide the required reports to the NPDB under the federal statutory and regulatory terms applicable to this federal database.

On the issues relevant here, the Guidebook is clear and unambiguous. First, the Guidebook states that "a surrender of clinical privileges or failure to renew clinical privileges while under investigation or to avoid investigation must be reported." Guidebook, at E-36. As previously noted, it continues:

> NPDB interprets the word "investigation" expansively. It may look at a health care entity's bylaws and other documents for assistance in determining whether an investigation has started or is ongoing, but it retains the ultimate authority to determine whether an investigation exists. The NPDB considers an investigation to run from the start of an inquiry until a final decision on a clinical privileges action is reached. In other words, an investigation is not limited to a health care entity's gathering of facts or limited to the manner in which the term "investigation" is defined in a hospital's bylaws. An investigation begins as soon as the health care entity begins an inquiry and does not end until the health care entity's decision-making authority takes a final action or makes a decision to not further pursue the matter.

Id. at E-36 through E-37. The Guidebook reiterates that "[f]or NPDB reporting purposes, the term 'investigation' is not controlled by how that term may be defined in a health care entity's bylaws or policies and procedures." *Id.* at E-37.

For purposes of PSVMC's federal obligations to report to the NPDB, when Dr. Corman, Dr. Douville, and Ms. Park met on February 12, 2021, to discuss the Datix reports submitted by Dr. Lee and Ms. Caine, PSVMC had begun its inquiry into the conduct of Dr. Owens. From the perspective of the NPDB, that is an investigation, no matter what PSVMC's Professional Staff Policies and Procedures, Bylaws, or other documents may say.

In addition, as previously noted, there is no requirement in the context of NPDB reporting that the health care practitioner be notified or aware of the investigation. Guidebook at E-37 ("[T]here is no requirement that the health care practitioner be notified or be aware of the investigation."); *see also* Guidebook at E-47 ("[T]he physician's awareness of the investigation is immaterial."). Even so, on February 26, 2021, Dr. Corman told Dr. Owens by email that Dr. Corman was sending that email in his role as Division Chief and that Dr. Owens should watch for an email from Abbie Goldberg, the Medical Staff Coordinator, about setting up a meeting to discuss "some recent concerns." Corman Decl. ¶ 5. Even if Dr. Owens had not yet been given precise details about the nature and scope of the investigation, he was not completely in the dark as of February 26, 2021. Indeed, when Dr. Owens did follow up by providing dates for his availability as he promised he would in response to Ms. Goldberg's email from March 1, 2021, Dr. Corman sent another email to Dr. Owens on March 10, 2021, emphasizing the need to meet soon and asking Dr. Owens to contact Ms. Goldberg. *Id*. ¶ 7. There was no response from Dr. Owens, even though he signed his Separation Agreement with TOC two days later. Owens Decl. ¶ 11.

On March 18, 2021, Ms. Goldberg left a voicemail for Dr. Owens; he responded by email on March 26th, stating that he was "fine" with switching his status with PSVMC to "inactive." Park Decl. ¶ 14. Ms. Goldberg replied one hour later and told Dr. Owens that even if he went to inactive status, he would still need to meet with PSVMC's physician leadership. *Id*. Dr. Owens responded within 21 minutes by stating: "No need for meeting. I resign my membership." *Id*. Based on these facts, it does not appear likely that Dr. Owens was unaware that PSVMC was investigating some aspect of his conduct and actions, even if he did not yet know all the details.

In a letter sent by email and overnight delivery on March 31, 2021, PSVMC explicitly told Dr. Owens that he was under investigation and needed to decide by April 5th whether he still wanted to resign or if he instead wished simply to go inactive. Owens Decl., Ex. 5, at 3. PSVMC also explained the consequences of each alternative. PSVMC told Dr. Owens that if he continued to request resignation, PSVMC would have to inform the NPDB that it accepted Dr. Owens's resignation while he was under investigation. *Id*. On the other hand, if Dr. Owens chose not to resign but instead to move to inactive status, he would still have to cooperate with the ongoing investigation. *Id*. On April 4, 2021, Dr. Owens told PSVMC that he contended that it was "inappropriate to say there was an investigation," but he did not ask to be placed on inactive status. *Id*. at 1.[9] On April 5, 2021, PSVMC accepted Dr. Owens's surrender of his clinical privileges, and on April 22nd reported to the NPDB that it had accepted Dr. Owens's surrender of hospital privileges while Dr. Owens was under investigation. Park Decl. ¶¶ 17, 19. As discussed above, federal law required PSVMC to file its report with the NPDB.

Finally, as described both in the regulations and the Guidebook, Dr. Owens can dispute PSVMC's report to the Secretary of the Department of Health and Human Services. Guidebook at F-3 through F-18. He also can add his own "Subject Statement" to the report. *Id*. at F-2 through F-3. The Subject Statement then "becomes part of the report and remains with the report unless the subject of a report edits or removes it. The Subject Statement is sent to the reporting entity and all queriers who received a copy of the report within the past three years, and it will be included with the report when the report is released to future queriers." *Id*. This will allow

[9] During oral argument, counsel for Dr. Owens stated that Dr. Owens had to surrender his hospital privileges to comply with the noncompetition provision contained in the Separation Agreement between Dr. Owens and TOC. Counsel for PSVMC responded that Dr. Owens could have complied with those obligations merely by switching to inactive status but then would have had to cooperate in the investigation.

Dr. Owens to ensure that anyone who receives a copy of PSVMC's report about him also will receive Dr. Owens's explanation of what happened.

Health care entities reviewing the NPBD makes their own decisions. The purpose of the NPDB simply is to ensure that health care entities have all the relevant information they need to make informed personnel decisions. *See* Guidebook at A-7, E-1. Dr. Owens does not appear to have either disputed PSVMC's report before the Secretary or submitted his own explanation (or Subject Statement) to be available alongside the report. Instead, he asks this Court to order PSVMC to withdraw its legally mandated report. On the state of the present factual and legal record, the Court declines to do so.

CONCLUSION

The Court denies Plaintiff's Motion for Preliminary Injunction (ECF 16).

IT IS SO ORDERED.

DATED this 29th day of August, 2022.

/s/ Michael H. Simon
Michael H. Simon
United States District Judge